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U.S. FDA says Glaxo failed to report Avandia data

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By Lisa Richwine

WASHINGTON (Reuters) - GlaxoSmithKline Plc failed to report all of the required post-approval data on its diabetes drug Avandia to U.S. regulators, the Food and Drug Administration said in a warning to the company released on Tuesday.

A strong warning about heart attack risk was added to the drug in November, and Glaxo said the FDA had received all the information before that decision was made.

In a letter to GlaxoSmithKline Chief Executive Jean-Pierre Garnier, the FDA said an inspection from August through November 2007 found Glaxo did not list multiple post-approval studies as required in various reports dating back to 2001.

"The specific violations in this letter are serious and may be symptomatic of underlying postmarketing safety reporting failures," the FDA said in the letter, which was dated March 25 and posted on the agency's Web site on Tuesday.

GlaxoSmithKline spokeswoman Nancy Pekarek said the omissions were "inadvertent" and the information did not raise any new safety concerns.

Nine studies were not disclosed to the FDA until September 2007, the FDA letter said. The company failed to include 11 others in required annual reports, although the FDA and Glaxo said that information was given to the agency in other ways.

The information included the start and progress of clinical trials and summaries of final data from some trials, the company said.

Glaxo Chief Medical Officer Ronald Krall said in a statement that the reporting omissions "did not interfere with the timely reporting of adverse event information to the FDA."

Avandia's 2007 global sales were $1.56 billion.

FDA officials ruled in November that Avandia could stay on the market but needed a "black box" warning, the strongest type, saying the medicine may increase the risk of a heart attack.

The British drugmaker said it was providing additional training to employees on reporting requirements and taking other steps to address the concerns raised in the FDA letter.

The FDA sends dozens of warning letters per year. Most issues are resolved without further action, but the FDA can impose fines or other penalties.

Glaxo shares fell 3.6 percent to $43.41 in early afternoon trading on the New York Stock Exchange.

The FDA letter was posted here

(Reporting by Lisa Richwine, editing by Maureen Bavdek and Gunna Dickson)